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July 21, 1986

Robert Brink, Ph.D.
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Dear Bob:

We have recently obtained a draft copy of the information review on Methyl tertiary butyl ether (MTBE) which was developed as a collaborative effort by CRCS, Inc. and Dynamac Corporation. It is our understanding that this document may serve as the basis for further EPA Interagency Testing Committee (ITC) action on MTBE.

After consultation with individuals from the scientific and business areas within ARCO Chemical Company and in Atlantic Richfield Company, comments have been prepared on the MTBE information review. These comments cover differences in interpretation of the data as well as provide new information that is expected to be beneficial to the ITC in any further analysis on this material.

If you or the other members of the ITC have any questions concerning this document, I would be happy to discuss these issues in detail. If not, I will follow-up with a telephone call in a week or two after you have had time to examine our comments.

Best personal regards.

Sincerely yours,

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Methyl-tertiary Butyl Ether

Critique of the CRCS, Inc./Dynamac Corporation Information Review

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Executive Summary

CRCS, Inc. and Dynamac Corporation collaborated on the development of an information review on Methyl tertiary butyl ether (MTBE) for use by the Interagency Testing Committee. Values derived from the Fifth Scoring Exercise, which occurred in 1983, were included in this draft information review. These scores represent arbitrary numerical ratings for eight different toxicological endpoints.

A critique of the CRCS/Dynamac report revealed that some erroneous assumptions had been made that cause the potential hazards of MTBE to be seriously overestimated. The report assumes that MTBE is present in all finished gasolines and does not consider that other octane-enhancers may be used. This also causes estimates of exposure and risk to be greatly exaggerated. The figures from the Fifth Scoring Exercise further confuse the issue because they are not indicative of the information that currently exists on the toxicological, environmental, and occupational exposure data for MTBE. Therefore, it is recommended that the information review be revised to more accurately reflect the existing information.

Introduction

An information review on Methyl tertiary butyl ether (MTBE) was performed by CRCS, Inc. and Dynamac Corporation in a collaborative effort for the Interagency Testing Committee. The working draft of this report, dated March 7, 1986, was provided to ARCO Chemical Company by the corporate toxicology group at Atlantic Richfield on May 30, 1986.

Each section of the CRCS/Dynamac report was reviewed in accordance with the available information listed in the bibliography. For comparison purposes, the critique that follows is in the order that the information appears in the original report and not in order of importance.

Overview

Characteristics - Moderate water solubility is reported. However, an ARCO Technical Bulletin states that "MTBE is only slightly soluble in water, but is miscible with most organic solvents"(1). The solubility of water in MTBE is 1.4 wt.% and 4.3 wt.% for MTBE in water at 68°F(1).

Production and Use - MTBE is used as an octane-enhancer in some, but not all gasolines. Current wording suggests that MTBE use is more widespread. Although it has been approved for blending up to 11 vol.% in finished gasoline, the actual concentration is dictated by the gasoline producer's octane needs and is usually between 2-8 vol.% (1,2).

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Toxicological Information - All genotoxicity studies were negative with the exception of the mouse lymphoma assay. In this study, a positive finding was seen only with exogenous metabolic activation. Since other *in vivo* and *in vitro* mutagenicity studies were negative, this single finding may be a spurious or "false positive" result. This conclusion is further supported by the fact that the mouse lymphoma assay has been known to produce "false positive" results with a number of unrelated test materials. Therefore, there is no basis for the CRCS/Dynamac conclusion that "genotoxicity studies on MTBE gave conflicting results"(3). This point will be discussed again later in this paper.

Environmental Information - The report erroneously concludes that MTBE would "partition to the atmosphere where it would be rapidly oxidized"(3). Cox and Goldstone have stated that MTBE has a relatively low photochemical reactivity for oxidant formation(4,5).

Summary of Hazard Potential - The CRCS/Dynamac report concludes that potential human exposure is high among workers and the general population. An analysis of the available information suggests that this conclusion is exaggerated. While it is possible that exposures could occur in the manufacture, storage and distribution of MTBE, the expected levels are very low and would be confined to areas of production and use.

Manufacturing occurs in a closed system which minimizes both worker exposure and loss of product. Grab sample measurements in the workplace are generally less than 3 ppm(6).

Table A presents industrial hygiene monitoring data for an MTBE operating unit(6). These data were obtained in April of this year and are considered to be "breathing zone" samples. Sampling was conducted using large SKC charcoal tubes (Lot #120) and DuPont P 125A sample pumps. The analysis of the charcoal tubes was performed by an independent, outside contractor.

Table A

Sample #	Job Title	Flow Rate (cc/m)	Time (min.)	Results (ppm)
1	Operator B	52	515	3.09
2	Operator B	50	527	2.78
3	Operator B	55	540	0.67
4	Area sample	50	225	1.27
5	Area sample	52	230	1.01

As the report itself states, Phillips Petroleum presents an average occupational exposure of 1.42 ppm (8 hour TWA) which corroborates these grab sample measurements(3).

Exposures to MTBE would be equally limited in transportation and loading operations. Grab samples for barge loading were similar

to the values obtained in the workplace (<2 ppm)[6]. Average exposures for dockworkers were determined to be 1.23 ppm[6]. Low transportation exposures are further supported by Halder, et al. in a study characterizing workplace exposure to gasoline vapor [7]. The authors of that study reported "overall 8-hour time weighted average (TWA®) geometric means of 5.7 mg/m^3 (1.4 ppm)" for gasoline terminals and "4.0 mg/m^3 (1.0 ppm) for the service plaza". While MTBE is not present in all gasolines, when it is used, blending concentrations are generally about 2-8 vol.%. The figures for gasoline exposure of 1.4 and 1.0 ppm, respectively, mean that MTBE exposure would, indeed, be negligible for transportation workers, service station attendants, and consumers.

The CRCS/Dynamac report states that potential environmental exposure is "high". This conclusion is not supported by the available information. This point will be discussed in greater detail later in this paper.

I. Chemical and Physical Information

MTBE is a clear liquid with a terpene-like odor[1,5]. As previously stated, solubility in water is more appropriately characterized as "slight" instead of "moderate"[1]. Studies have been conducted and reported by Reynolds, Smith, and Steinmetz on the potential for peroxide formation by MTBE[8]. Their work indicates that peroxides are not formed with MTBE and does not support generalization from other alkyl ethers.

II. Exposure Data

The report lists Texas Butadiene Company and Texas Petrochemicals Corporation as manufacturers of MTBE in 1984. A review of manufacturers and production figures for 1983-1986 did not show that Texas Butadiene Company made MTBE in any of the years searched[9-14]. Texas Petrochemicals Corporation was under construction in 1984 and was not commissioned until 1985 when a relatively small amount of MTBE was produced in comparison with the other manufacturers[10,11,13].

Table 1 of the CRCS/Dynamac report presents the respective nameplate capacities of the domestic manufacturers of MTBE in 1984. Some of the values reported appeared to be higher than could be substantiated from the available sources for that year. However, these figures are more indicative of production capacities for 1985[13].

The CRCS/Dynamac report contains a single sentence on page 5 indicating that MTBE is used alone and as a 50:50 blend with methanol. A search of the literature did not yield any information on the industrial use of MTBE alone. It has been used in medicine on an experimental basis for the dissolution of cholesterol gallstones in humans[15-22]. The statement that MTBE is consumed as a commercial product containing 50% MTBE and 50%

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methanol is erroneous. At present, methanol cannot be used as a fuel additive in combination with MTBE at these concentrations unless a waiver is obtained from EPA. To date, no such wavier has been applied for or granted.

Section B on use is somewhat misleading, because as previously stated, MTBE is not blended into all gasolines. Therefore, gasoline consumption and MTBE use are not directly related. Other octane-enhancers may also be used instead of MTBE.

Occupational exposure would be limited due to the closed process for manufacturing. MTBE production is also an automated operation that is not labor intensive. In one high volume facility (>800 million lbs/year), only one operator is required per shift[23]. Two operators are required per day for a total of four operators per week according to current work schedules. Since the majority of producers manufacture lower volumes of MTBE, only a limited number of workers could be expected to be potentially exposed throughout the entire domestic industry.

The CRCS/Dynamac report perpetuates two important overestimates of worker exposure. First, the report quotes a NIOSH estimate that "2,571 workers ... were potentially exposed to MTBE in the workplace in 1980." This figure does not seem proportionate to the low number of producers in that year nor is it consistent with the automated, closed process. It is probably even an overestimate of the number of workers involved in current domestic production. The second overestimate stems from an unreferenced source that one low volume refinery ($\simeq$ 4,000 lbs/day) reported that 72 workers were potentially exposed to MTBE for greater than 150 man-hours per year. These results are not consistent with figures from a high volume producer and seem highly questionable[23].

Conclusions presented in the report for potential consumer exposure are clearly based on an inadequate understanding of the facts related to MTBE. As has been repeatedly stated, total gasoline use and MTBE use are not directly proportional because it is not blended into all gasolines. Other octane-enhancers may also be used. Halder and coworkers have presented data that exposures to gasoline vapor at the service plaza are approximately 1.0 ppm (8 hr. TWA)[7]. MTBE could account for only a very small fraction of this value due to restrictions on blending concentrations and the type of feedstock used. Tests performed in 1983 by ARCO Petroleum Products Company indicated that MTBE accounted for approximately 3.3% of the organic vapors in the head space above gasoline containing 10% MTBE[5,24]. The increased use of vapor recovery systems at service station pumps would be expected to reduce this value further.

Exposure from accidental spills of MTBE could occur, but should be regarded as a minimal possibility. The closed nature of the manufacturing and transportation process reduces worker exposure and product loss. Training and safety programs also lower the

possibility of accidental spills. Many current programs at EPA and in industry are underway to monitor and reduce the possibility of gasoline loss from leaking underground storage tanks. MTBE would be lost from these tanks only if it were a constituent of the gasoline in the tank. MTBE losses would be extremely small from this source.

II. F. Scores from the Fifth Scoring Exercise

The Fifth Scoring Exercise was conducted by contractors for the TSCA Interagency Testing Committee during the period from January to August of 1983 when 82 chemicals were selected for in-depth review[25]. MTBE was one of the materials selected to undergo further analysis. CRCS, Inc. and Dynamac Corporation have evidently copied the 1983 scoring values for MTBE into their latest information review document. Unfortunately, these three-year-old scores do not reflect what is currently known about potential exposures or possible biological effects. These values are difficult to understand in the information review because, (a), the necessary criteria for interpretation are reported separately in an unreferenced document and, (b), the indices certainly do not reflect the data available to CRCS and Dynamac for review in 1985-6[25].

For clarification purposes, the scoring values and their meaning have been derived from the CRCS/Dynamac report, the results of the Fifth ITC Scoring Exercise and a personal communication with W. Perry of Dynamac Corporation[3,25,26]. Exposure scores for MTBE are shown in Table B:

Table B

Results of Fifth Scoring Exercise for MTBE [3,25]

Exposure Indices	Interpretation*
Occupational exposure index - 0.62	"0.5 and above (high exposure)"
General population exposure index - 0.46	"0.5 and above (high exposure)"
Environmental exposure index - 0.22	"0.4 and below (not ... exposure)"

*The interpretation of each of the exposure indices was provided by W. Perry of Dynamac Corporation who served as the project director on the report of the Fifth ITC Scoring Exercise. He was contacted because no reference to criteria for evaluation of the final exposure scores was found in the final ITC report.

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The values for occupational, environmental, and general population exposure appear to be based largely on the contractor's projections for the quantity of MTBE produced and on an erroneous assumption that MTBE is blended into all finished gasolines. Assumptions were made in the absence of hard data for occupational and general exposure levels that caused the scores to be unrealistically high. If the scores were recalculated on the basis of the data that currently exist, the values would probably not result in a conclusion of high exposure potential.

Table C presents the scoring values indicative of the toxicological hazards of MTBE:

Table C

Biological Effects Scores(3,25)

Mutagenicity - (+ 2.0) "Positive in vitro mutagen, and interacts specifically with germinal-cell DNA in vivo"

Carcinogenicity - (- 2.0) "No experimental data; some reason for suspicion based on structural similarity to known mutagen or carcinogen"

Teratogenicity - (- 1.0) "No experimental data; no reason for suspicion"

Reproductive Effects - (- 1.0 "Needs testing; no reason for suspicion (absence of data)"

Acute Toxicity Effects - (+ 1.0) "Moderately toxic"
"Acute oral LD_{50} = 0.5-5g/kg"
"Acute dermal LD_{50} = 50-500 mg/kg"
"Acute inhalation LC_{50} = 50-500 ppm"

Other Toxic Effects - (- 2.0) "Needs testing; some reason for suspicion"

Bioaccumulation - (0.0) "Experimental evidence for nonaccumulation (less than 1); water-soluble compounds"

Ecological Effects - (- 1.0) "No data, but no reason for suspicion"

Scores of biological effects will be discussed in conjunction with the biochemical and toxicological portions of this report.

III. Bicchemical Information

The metabolic study of MTBE clearly showed that ~ 90% of the injected material was recovered from the expired air as either MTBE or CO_2 within six hours. These data, in conjunction with the blood level data, tend to show that MTBE is readily absorbed

and rapidly excreted. Technical problems resulted in unreliable data for the tissues[27]. Because of the rapid distribution and excretion of MTBE, there should be no concern for chronic health effects due to the recognized low-level, short-term exposures.

IV. Toxicological Information

No carcinogenicity studies are known to exist for this material. However, evidence from both the in vivo and in vitro studies indicates that MTBE has a low order of toxicity. The participants in the Fifth ITC Scoring Exercise rated carcinogenicity as a -2.0 because they concluded that there was "no experimental data [and] some reason for suspicion based on structural similarity to [a] known mutagen or carcinogen"[25].

A single positive response in one half of one mutagenicity test is not sufficient evidence on which to base the above conclusion. MTBE was negative in the mouse lymphoma assay without activation. The number of "false positive" responses for this assay alone should cast doubt about any major conclusions.

Comments by the American Industrial Health Council (AIHC) to EPA do not support single assay triggers for determinations on the need to initiate extensive bioassay studies[28]. These comments state, "published literature demonstrates that no single genotoxicity test can predict mutagenicity or carcinogenicity for all classes of compounds". Instead, AIHC stresses that "uncertainty about certain modes of action of genotoxic carcinogens may influence the selection and applicability of specific carcinogenicity assays".

It would be difficult to make a strong case that MTBE is a structural analogue of a known carcinogen. Bis(chloromethyl)ether has long been known to be a carcinogen, but is very unrelated to the structure of MTBE. Therefore, no conclusion on the carcinogenicity of MTBE can be made in view of the available information.

All genotoxicity studies on MTBE were performed by ARCO Chemical Company and provided to the American Petroleum Institute[29]. This is in contrast to what is stated in the report.

A battery of mutagenicity studies was conducted in order to develop a more complete information base on MTBE than would be the case if only a single assay were conducted and interpreted. Two samples were completely negative in the Ames Salmonella and Saccharomyces tests both with and without activation. Other negative assays included an in vivo cytogenetic study, a sister chromatid exchange and chromosomal aberration assay, and the mouse lymphoma study without metabolic activation.

The CRCS/Dynamac report tends to lead the reader to what would be an erroneous conclusion in its discussion of the sister chromatid exchange assay in Chinese hamster ovary cells. Although there

was a slight elevation in the number of sister chromatid exchanges per cell only with S-9 addition at dose levels of 0.2 ul/ml and 1.0 ul/ml, in one sample, it failed to meet the criteria for a positive response and should, therefore, not be considered positive overall. No evidence of a clastogenic effect was reported.

It should be noted that a further screening study was conducted to better understand the results of the mouse lymphoma study with the activated system. ARCO initiated a study to determine if an intermediate metabolite such as methanol or formaldehyde might be responsible for the single positive finding[29]. This screening test was conducted based on the hypothesis that MTBE would be metabolized first by hepatic mixed function oxidase to form formaldehyde and t-butyl alcohol, then further metabolized by other S9 enzymes to either formic acid or methanol. The results indicate that formaldehyde was the initial metabolite in the presence of either S9 or mixed function oxidase and was readily metabolized by these enzymes to other materials. It was suggested by the authors of the report that the positive response in the mouse lymphoma assay may be a "false positive" because this assay is especially sensitive to aldehydes and alcohols[30].

Considerable work has been performed to understand and interpret the mutagenic potential of MTBE. The Fifth Scoring Exercise rates MTBE as +2.0 for mutagenicity. This indicates that there is "positive in-vitro mutagenic activity and interacts specifically with germinal cell DNA in-vivo[25]. There is no evidence from the mutagenicity assays reviewed by CRCS/Dynamac that MTBE could be so categorized.

MTBE has been studied in rats and mice for potential teratogenicity and embryotoxicity. The results of these studies have recently been published by Conaway, Schroeder and Snyder[31]. This causes the results of the Fifth Scoring Exercise to be misleading because the numerical value is not based on actual data supplied to CRCS/Dynamac[25].

A single generation reproduction study was conducted by an API ad hoc industry group in CD rats[32]. Again, the Fifth Scoring Exercise indicates with a -1.0 rating that testing is needed, when it has, in fact, been completed[25].

ARCO Chemical Company conducted a battery of acute toxicity tests on MTBE[29]. Dermal irritation studies on two samples produced either no irritation or only slight irritation. An eye irritation study in rabbits also resulted in slight irritation. The oral LD_{50} in rats was 3,865.9 mg/kg (slight toxicity) and the dermal LD_{50} was greater than 10,000 mg/kg. The 4 hour inhalation LC_{50} was calculated to be 39,461 ppm with 95% confidence limits of 33,332.5 and 46,718.9 ppm. A dermal sensitization study in guinea pigs was negative. The ITC scoring system rating of +1.0 (moderately toxic) appears to be in conflict with the data presented and with other rating systems in use[33-35].

Subchronic toxicity studies have been conducted on MTBE. A nine day study was performed under contract to an API ad hoc committee that was used to set doses for later reproduction/teratology studies[36]. A three month inhalation study was performed by Chemische Werke Huls AG which the CRCS/Dynamac report incorrectly attributes to API[37]. The Fifth Scoring Exercise rated subchronic and other toxic effects as -2.0 for "needs testing: some reason for suspicion[25]. The negative results of these two subchronic studies do not support this conclusion.

Using the actual data available, the Biological Effects Scores should be as follows:

Mutagenicity	0	"Adequately tested with negative results"
Carcinogenicity	-1	"No experimental data; no reason for suspicion"
Teratogenicity	0	"Adequately tested with negative results"
Reproductive	0	"Adequately tested with negative results"
Acute Toxicity	0	"Very slightly toxic"
Other Toxicity	0	"Very low or negligible biological activity"
Bioaccumulation	0	"Experimental evidence for non-accumulation (less than 1); water soluble compounds"
Ecological Effects	-1	"No data, but no reason for suspicion"

indicating that MTBE is a relatively innocuous chemical and testing should be reserved for chemicals of more potentially serious concern.

V. Observations in Humans

No comments have been made on this section.

VI. Environmental Information

As has been repeatedly stated, environmental entry would not occur in every stage of the gasoline marketing chain. Releases are only possible if MTBE has been used in a particular gasoline and would, then, be dependent on the amount used in blending. Environmental entry of MTBE from this source would be considerably less than the report indicates.

MTBE is only slightly water soluble so environmental fate projections based on this assumption will not be correct[1,5].

Darnell and coworkers conducted studies on ethers other than MTBE[38]. Their assumptions are not relevant to this chemical since actual data have been developed by Cox and Goldstone[4,5]. Data indicates that the reaction of OH with MTBE is slow relative to OH attack on propene and n-hexane which are automotive emissions. MTBE is thus, of relatively low photochemical reactivity for oxidant formation with relatively long atmospheric residence times of about three and one-half days[5].

Smog chamber studies were carried out by Stanford Research which allowed comparison of the results of irradiation of exhaust and evaporative emissions from a vehicle operating on a base hydrocarbon-only gasoline to results obtained with emissions produced while operating on a 15V% MTBE/gasoline blend. Comparisons of (1) Eye irritation as evaluated by "human subjects", (2) rate of formation of nitrogen dioxide, (3) rate of disappearance of hydrocarbons, (4) maximum level of oxidant produced, and (5) concentrations of other products such as formaldehyde and peroxyacetyl nitrate were made.

The conclusion drawn by the investigators was that the tests showed no increase in reactivity of exhaust or evaporative emissions that could be attributed to the addition of MTBE.

The section on biodegradation should have also indicated that Fujiwara, et al. stated that their studies showed that MTBE-blended gasoline "causes no environmental pollution"[39]. The summary section should be corrected to indicate that MTBE is subject to relatively low photochemical reactivity for oxidant formation. Figure 1 should be adjusted accordingly.

Summary and Conclusion

The CRCS/Dynamac report suffers from three major problems. First, an incorrect assumption is made that MTBE is present in all gasolines and that exposure and release are synonymous. The second major defect in the report is that incorrect conclusions have been made which significantly overestimate exposure and consequently risk. The third problem is that addition of the values from the Fifth Scoring Exercise in 1983 only serve to confuse the reader because they do not represent the current state of knowledge on MTBE nor even the data in the review. Therefore, it is recommended that the CRCS/Dynamac report be revised to reflect what is known about biological, environmental, and occupational aspects of methyl tertiary butyl ether production and use.

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[M/6/30/BKH/SAR/MTBE]